

Guidance on Completing and Reviewing the New GREB Standard <u>Application Form</u>

This document is intended to highlight important advice and guidelines for completing the new GREB form.

If an item is not mandatory (indicated by an asterisk) and is not applicable to the research, it can be left blank.

Section 1 Reviewers do <u>not</u> review this section. The Ethics Coordinator will review the ethics file for CORE completion requirements.

- 2.3 The Abstract is a memory aid for reviewers when they are discussing the application. Its new word limit is 200 words, rather than the previous 300-500 words. The Abstract should not exceed 200 words.
- 2.4 The Method should describe what data collection entails in sufficient detail so that the reviewer could carry out the study. It should not, however, be a dump for a research proposal designed for other purposes (e.g., funding requests, graduate research proposals); hence, the 1000-word limit. The method should not include field specific jargon and should be written so that an educated, non-specialist would be able to understand it. The Method can exceed 1000 words **only** if the research is complex with multiple studies or phases. Aspects of your project that do not involve human participant ethics do not need to be described in detail (e.g., document analysis). You do not need to repeat **all** information that is included in other sections of the application form (e.g., recruitment, withdrawal procedures, compensation, risks) but instead provide a summary as applicable.

Emergent research designs should outline research procedures as clearly as possible, even though exact research procedures will only be finalized when the research is happening. These alterations can be approved through an amendment.

If the Method is so vague that the reviewer cannot understand what is going to take place, the reviewer can legitimately return the application to the researchers without further review.

Two major issues ensue with item 2.4 (both of which must be addressed by the researcher):

- a) Important details are missing;
- b) Information in 2.4 is not congruent with other information in the application or with information being provided to the participants.

Although there is a requirement that ethical review be methodologically sound, reviewers should be careful with respect to making suggestions about the method's applicability or rigour, in that reviewers are not experts in the methodology of the particular field.

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- 2.9/2.10 REBs are independent from OCASP. These questions are designed to remind researchers of their need to be aware of OCASP.
- 2.11/2.12 GREB only clears research for Queen's University. It does not clear or approve research for other institutions. Researchers need to be made aware of likely other institutions where ethics clearance or approval (depending on the terminology used) needs to be sought.
- 2.13 There is a GREB Secondary Use of Data Application Form for Data Sets Initially Collected with an Associated Research Ethics Clearance and for Publicly Available Anonymous Data for researchers who are only using secondary data, rather than a combination of primary and secondary data. Refer to the GREB Secondary Use of Data Guidelines document to determine if criteria have been met to use this application form.
- 3.1 Numbers provided in this section should be derived from the nature of the research study, the type of data being collected, and the volume of previous research in the area. The maximum number should be reasonable. If the size of the sample is underestimated, the researcher will be required to submit an amendment at a later date to increase the sample size.
- 3.5 The important word is "specifically." If Indigenous participants are not a focus of the study, the answer should be "No."
- 3.7 Researchers tend to answer this item about recruitment quite vaguely. Specificity is necessary to increase the likelihood of equitable recruitment procedures and to help ensure that recruitment leads to informed and voluntary consent. Recruitment materials must be attached.
- 3.8 Because GREB understands that participants cannot actually withdraw after the publication of their data, we are giving researchers the option to suggest a time for withdrawal commensurate with publication, rather than "at any time." Anonymous data cannot be withdrawn after submission.
- 3.9 Compensation, if offered, should be reasonable. Reasonableness is dependent on the amount of time required and the circumstances of the participants. Compensation must be provided should the participants withdraw at any point (including right after providing consent). It is recommended that longer studies with high levels of total compensation be broken into phases with compensation provided per phase with completion of one phase required before commencement of the next phase. Compensation should not be so high as to be coercive. Compensation should not be the focus of recruitment materials. For additional guidance refer to "Incentive Guidelines for Human Participant Research," which is posted on GREB's website.
- 4.1 Some researchers understate risks, especially indicating that there are "no known risks" when risks exist. Other researchers overstate risks, listing any possibility, no matter how unlikely. Selected risks should be reasonable. The judgment for reasonableness is a balance between likelihood and severity. For example, it may be reasonable to include severe risks even if they are unlikely to occur.

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The single biggest error in GREB ethics applications may be a failure to match risks listed in this item and risks conveyed to participants in the Letter of Information.

- 4.2/4.3 Questions about sensitive or personal issues, psychological risks, physical risks, economic risks, and social risks are an inherent part of the research. These inherent risks should be mitigated as far as possible and listed in the Letter of Information. Dangerous location, such as war-torn country; risks to participants due to power imbalance; and language and/or cultural sensitivities are not an inherent part of the research but reflect the context in which the research is being carried out. Researchers should be aware of these contextual risks and take steps to mitigate or eliminate them. Contextual risks are not generally listed in the Letter of Information.
- 5.1 Much research has no direct benefits to participants. GREB would prefer researchers acknowledge that their research has no direct benefits to participants rather than try to "create" benefits. GREB requires that benefits be stated in the Letter of Information.

Compensation is not a benefit.

- 6.1/6.2 It is helpful to refer to the Info Box in item 6.1 for a description of what constitutes "personally identifiable information." Videotaping, which provides a wealth of personally identifiable information, should only be used when the research requires analysis of visual data, rather than just audio data. Any use of video and/or audio recording must be justified with respect to its collection of personally identifiable information.
- 6.3 This item does not include information obtained solely for recruitment purposes (covered in item 3.7).
- 6.4 This item does not include information shared within the research team (including those individuals who have signed a Confidentiality Agreement).

